K070205

1. 510(K) SUMMARY - BASIC INFORMATION

This 510(k) Summary is prepared in accordance with 21 CFR 807.92.

MAR 2 3 2007

1.1 SUBMITTER

Applicant: Ziosoft, Inc.
7th Floor, TTD Building
1-2-18 Mita, Minato-ku
Tokyo, 108-0073 Japan

Contact: Marc Goodman, Noblitt & Rueland
5405 Alton Parkway, Suite A530
Irvine, CA 92604
USA

Date Prepared: January 18, 2007

1.2 DEVICE NAME

Device Name:	ZIOSTATION
Common Name:	Image processing, management and visualization system
Classification Name:	System, Image Procession, Radiological

1.3 IDENTIFICATION OF LEGALLY MARKETED DEVICE

Substantial equivalence is claimed to the Barco *Voxar 3D Enterprise* (K061326).

1.4 DEVICE DESCRIPTION

ZIOSTATION is a software-only imaging workstation that installs on one or more of a customer's standard PCs and integrates with a customer's 'off the shelf' PC-based computer components to provide viewing, quantification, manipulation, communication, printing, and management capabilities for medical images. It provides access to both local and centralized (networked) image data.

ZIOSTATION can acquire and work with image data from multiple DICOM-compliant modalities and image archives. It provides querying and listing based on user-selected criteria. It provides for multiple types of 2D and 3D image displays. It provides interactive menus and tools for image manipulation and measurement. ZIOSTATION provides workflow enhancement and optional specialist tools for clinical applications.

ZIOSTATION uses only lossless compression for images used for diagnostic purposes. It does use lossy compression when exporting to JPEG and AVI files, but its labeling indicates that those files are not to be used for clinical evaluations.

1.5 INTENDED USE

ZIOSTATION is an image processing workstation software package designed to run on standard PC hardware. The required hardware consists of standard 'off-the-shelf' computer components. It receives image data from standard modalities (medical image scanning devices) or from image archives. It provides for the viewing, quantification, manipulation, communication, printing, and management of medical images. It can be

used as a just a workstation or as a client-server within a network. It is intended for use by trained medical imaging professionals to aid in their reading and review of such data.

Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Mammograpic images may only be interpreted using an FDA approved monitor that offers at least 5 MPixel resolution and meets other technical specifications reviewed and accepted by FDA.

1.6 Comparison to Cleared Device

Table 1 provides a tabular comparison of ZIOSTATION features with those of the legally marketed devices identified in 1.3 above.

Table 1: Comparison of ZIOSTATION to SE Devices

Feature	ZIOSTATION	Voxar 3D Enterprise (K061326)
Basic Function	View, quantify, manipulate, communicate, print, and manage medical images	same
Computer Platform	PC with Windows OS	same
DICOM compliance	DICOM 3.0	same
Data Acquisition	Can acquire medical image data from multiple sources including DICOM files (from image archives) and multiple DICOM-compliant modalities.	same
2D Imaging	2D image viewer with interactive controls	same
3D Imaging	3D image rendering with interactive controls	same
Measurement Tools	yes	yes
Segmentation Tools	yes	yes
Remote Rendering	yes	yes
Clinical Applications	Provides (optional) specialist tools and workflow enhancements for clinical applications such as coronary, colon, and vessel analysis.	same
Prescription Use	yes	same
Intended Users	trained professionals	same

2. PERFORMANCE INFORMATION

ZIOSTATION has been thoroughly tested by Ziosoft in accordance with their software development and validation procedures, and it has been independently evaluated by trained physicians specializing in medical imaging disciplines.

3. CONCLUSION

Ziosoft has demonstrated that ZIOSTATION is safe and effective for its intended use. A comparison with legally marketed devices indicates that it is substantially equivalent to those devices, and that it does not raise any new safety or efficacy concerns.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Ziosoft, Inc.
c/o Mr. Marc Goodman
Senior Associate
Noblitt and Rueland
5405 Alton Parkway, Suite A530
IRVINE CA 92604

MAR 2 3 2007

Re: K070205
Trade/Device Name: ZIOSTATION
Regulation Number: 21 CFR §892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: January 18, 2007
Received: January 22, 2007

Dear Mr. Goodman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K070205

Indications for Use Statement

ZIOSTATION is an image processing workstation software package designed to run on standard PC hardware. The required hardware consists of standard 'off-the-shelf' computer components. It receives image data from standard modalities (medical image scanning devices) or from image archives. It provides for the viewing, quantification, manipulation, communication, printing, and management of medical images. It can be used as a just a workstation or as a client-server within a network. It is intended for use by trained medical imaging professionals to aid in their reading and review of such data.

Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Mammograpic images may only be interpreted using an FDA approved monitor that offers at least 5 MPixel resolution and meets other technical specifications reviewed and accepted by FDA.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE TO ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

David A. Lyman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K070205